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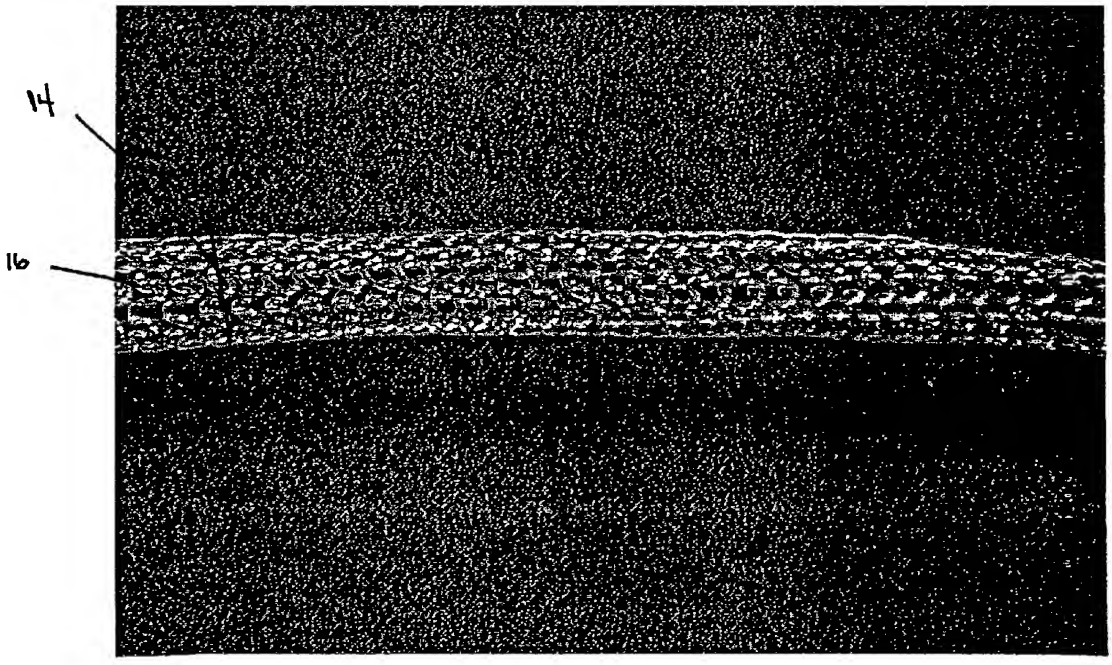

(57) Abstract: Implants (20, 22) and methods of making the implants for treating bodily defects or remodeling tissue. The implants have a low density and open pores (49) which may permit tissue ingrowth.

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Three Dimensional Implant

TECHNICAL FIELD

This invention relates generally to medical devices and more specifically to three-dimensional implants that can be administered to injured or otherwise defective tissue within the body.

BACKGROUND

Soft tissue implants are commonly used to reinforce or replace areas of the human body that have acquired defects. Several soft tissue implants have been developed and are commercially available. For example, Bard Mesh™ is a non-absorbable implant that is made from monofilament polypropylene fibers using a knitting process (C.R. Bard, Inc., Cranston, RI; *see also* U.S. patent 3,054,406; U.S. patent 3,124,136; and Chu *et al.*, *J. Bio. Mat. Res.* 19:903-916, 1985). This same material is used to construct other implants such as the Bard Mesh PerFix™ Plug, discussed further below.

Soft tissue implants have been used to treat many defects, including those that affect the abdomen and abdominal wall. For example, cylindrical plugs have been suggested for recurrences of inguinal hernia (Lichtenstein *et al.*, Am. J. Surg. 128:439-444, 1974), and an umbrella plug technique was subsequently described (Gilbert, *Perspectives in General Surgery* 2:113-129, 1991). Yet another technique for mesh plug hernioplasties was described by Rutkow in 1993 (Rutkow *et al.*, *Surgery* 114:3-8, 1993). Abdominal wall defects can also be addressed with the Bard Mesh PerFix™ Plug, which functions as an implantable and non-absorbable mesh prosthesis that can be used as a compressible and pliable implant (C.R. Bard, Inc., Cranston, RI; *see also* U.S. Patent Nos. 5,356,432 and 5,716,408; *see also* U.S. Patent No. 6,066,776). Implantable prostheses for repairing defects in muscle or other tissues can have a preformed shape that conforms to the shape of the defect. The shaped prosthesis may facilitate placement and minimize shifting (*see* U.S. Patent No. 5,954,767). Kits that can be used to repair indirect hernias are described in U.S. Patent No. 6,166,286, and a prosthetic device having an extension canal made of sheet material for extending through a hernia is described in U.S. Patent No. 6,241,768. An

implantable prosthesis containing a radially-expandable member for placement in and occlusion of a hernia opening is described in U.S. Patent No. 6,425,924.

The plugs described above are made using synthetic fiber technology. The implant surface area for the biomaterial used to construct the Bard Mesh™ has been calculated. The following formulas were used to calculate the surface area ratio for Bard Mesh:

$V_{mat} = W_{mat}/D_{mat}$ where V_{mat} is the material volume, W_{mat} is the material weight, and D_{mat} is the material density which is 0.904 g/cm^3 for polypropylene;

$L_{fiber} = V_{mat} /((\Pi)(R_{fiber})^2)$where R_{fiber} is the radius of the fiber and L_{fiber} is the length of the fiber;

$A_{surface} = (\Pi)(D_{fiber})(L_{fiber})$ where $A_{surface}$ is the surface area of the fiber used to construct the material and D_{fiber} is the diameter of the fiber; and

Surface Area Ratio = $A_{surface}/F_{area}$ where F_{area} is the area of the biomaterial fabric used to obtain W_{mat}.

Product	Construction	Weight (g/cm^2)	Fiber Diameter (cm)	Surface Area Ratio
ard Mesh	Monofilament Knit	0.0096	0.017	2.52

Bard Mesh™ is used to construct the Bard Mesh PerFix™ Plug. With values for the implant surface area for the Bard Mesh™ and the volume for the Bard Mesh PerFix™ Plug, the implant surface area to volume ratio can be calculated. The following formulas were used to calculate the surface area to volume ratio for the PerFix™ Plug:

$A_{surface\ plug} = (W_{plug}/W_{mesh\ cm2})*A_{surface\ cm2}$ where $A_{surface\ plug}$ is the surface area of the fiber used to construct the plug, W_{plug} is the weight of a size large PerFix Plug, $W_{mesh\ cm2}$ is the weight of Bard Mesh per cm^2 and $A_{surface\ cm2}$ is the area of the fiber used to construct Bard Mesh per cm^2;

$V_{plug} = ((\Pi)(L_{plug})(R_{plug})^2)/3$ where V_{plug} is the volume of the cone shaped plug, L_{plug} is the plug height, and R_{plug} is the plug radius at the base; and

Surface Area to Volume Ratio = $A_{surface\ plug}/V_{plug}$.

Product	Weight (g)	Plug Surface Area (cm^2)	Plug Volume (cm^3)	Surface Area:Volume
PerFix Plug (Large)	1.01	266	24.68	10.79

These implants are not ideal. Following are some of the disadvantages associated with one or more of the implants presently used. Where their construction results in substantial wall thickness, surface area, density, and/or interstices, there is an increased risk of inflammation and infection; loose or soft plug implants can collapse, leading to shrinkage during the healing process (up to 75%, which can fail to secure the intended repair); excessive scarring and shrinkage can cause plug implants to assume a cartilage-like consistency (which can erode into adjacent tissue such as the bladder, intestines, and blood vessels); in the event of neuralgia, plugs may have to be removed; material content and wall thickness can require large incisions (thus, utility in less invasive surgical procedures may be limited); seromas, caused by the host inflammatory reaction to the implant, and dead space can be created between the prosthesis and host tissue; rough implant surfaces can irritate tissues and lead to the erosion of adjacent tissue structures and adhesion to bowel when the implant comes in direct contact with the intestinal tract; non-absorbable implants may elicit a chronic foreign body response; implants having small pores may not permit adequate tissue ingrowth and incorporation; implants requiring a separate onlay require additional time to implant; and plug implants are prone to migration, even with the use of staples or sutures. Accordingly, there remains a need for devices for repairing soft tissue bodily defects.

SUMMARY OF THE INVENTION

The present invention features implants (*e.g.*, three-dimensional soft tissue implants) that can be used to treat bodily defects (whether arising congenitally or as a result of a disease, disorder, condition, or surgical procedure) or to remodel tissue (following, for example, a traumatic injury (such as a burn) or for cosmetic purposes). In addition, the invention features methods for making the implants and kits (*e.g.*, sterile kits that include an implant and, optionally, instructions for its application, and which can facilitate the surgical procedure in which the implant is used). In one

embodiment, the implants have a low density (*i.e.*, a low weight:volume ratio), a low implant surface area ratio (the fiber or material surface area divided by the material area), and open pores, which may permit tissue ingrowth following implantation into a patient (*e.g.*, a human patient). The surface area ratio can range from about 0.4 to about 4.0. For example, the surface area ratio can be approximately 1.0, 2.0, or 3.0 (*e.g.*, 0.6, 0.8, 1.0, 1.2, 1.4, 1.6, 1.8, 1.9, 2.0, 2.1, 2.2, 2.4, 2.6, 2.8, or 3.0; the implants of the invention can also be described as having a surface area ratio of less than 3.0), the surface area to volume ratio can range from about 2.0 to 4.0. For example, the surface area to volume ratio can be approximately 3.0 (*e.g.*, 2.0, 2.1, 2.2, 2.4, 2.6, 2.8, 3.0, 3.1, 3.2, 3.4, 3.6, 3.8, or 4.0), and the pore size can be approximately 50-2000 μ (*e.g.*, 50, 100, 200, 300, 400, 500, 600, 700, 800, 900, 1000, 1100, 1200, 1300, 1400, 1500, 1600, 1700, 1800, 1900, or 2000 μ; preferably, the pore diameter is measured before implantation, when the implant is in a natural, resting position). Thus, and as further described below, the methods of the invention can produce implants that are highly porous and of a low material content, yet strong enough to modify for repair tissue.

More specifically, the invention features a three-dimensional biocompatible implant, the implant comprising a subassembly that resists compression when implanted in a warm-blooded animal. The subassembly can include woven or braided fibers or can be produced using a circular weft or warp knitting process. In any event, the subassembly can be produced using an internal support (*e.g.*, PEEK). The implant of claim 1, wherein the subassembly is produced using a circular warp knitting process. The subassembly can also be produced using a nonwoven film and/or a substrate comprising pores as shown in Fig. 9C. The pores can be 50-2000 microns in diameter, and the implant can have a conical form and further include an only or anchor.

The invention also features a method for producing a three-dimensional biocompatible implant that includes one or more of the following steps:

a) extruding a biocompatible polymer into a fiber,

b) transforming the fiber into a compression resistant subassembly,

c) braiding or weaving the subassembly into a three dimensional structure,

d) heat setting the structure into the desired shaped article, and, optionally,

e) attaching the shaped article to a complementary implant article.

The invention also features a method for repairing a defective tissue in a patient (*e.g.*, a patient with a hernia), the method comprising applying the three-dimensional biocompatible implant to the defect by way of a surgical procedure.

The invention also features a kit comprising an implant, optionally sterile, as described herein.

The invention also features a method of delivering the implant of claim 1 to a patient's body, the method comprising exposing a defective tissue on or within the patient's body and placing the implant on or over the tissue. The implant can be compressed, by hand or by a device, prior to being placed on or over the tissue.

The method for producing a three-dimensional biocompatible implant, the method comprising one or more of the following steps:

a) extruding a biocompatible polymer into a film,

b) transforming the film into a subassembly,

c) shaping the subassembly into a three dimensional structure,

d) heat setting the structure into the desired shaped article, and, optionally,

e) attaching the shaped article to a complementary implant article.

The invention also features a three-dimensional implant comprising two or more layers of two-dimensional biocompatible material with interconnecting supports, said implant constructed to securely fit within a tissue or muscle wall defect.

The implants of the invention may have one or more of the following advantages. They can be configured to allow or stimulate fibrosis (or fibrotic tissue ingrowth) in an organized pattern (tissue ingrowth under these circumstances may provide additional support to the previously defective tissue); they can have a reduced surface area and/or density (reduced with respect to present implants) that minimizes the inflammatory response and infection risk to the patient; they can have a degree of compression resistance that minimizes shrinkage and erosion of the implant into adjacent tissue structures and reduces the likelihood of collapse after insertion; they can have stress-strain properties that are compatible with the mechanical properties of

the tissues they contact in the patient's body and therefore promote healing and minimize discomfort; they can be constrained (*e.g.*, held within a biocompatible (*e.g.*, non-toxic) tube or similar outer structure) and have a profile low enough to facilitate insertion and deployment within a patient in a minimally invasive fashion; they can be biodegradable or bioresorbable; and they can contain an onlay or anchor that can be secured in position in a short period of time. The anchor and three-dimensional soft tissue implant combination create a frictional force with the surrounding tissue to prevent migration. Implants that are less prone to migrate from the site of implantation can be used with fewer, if any, staples or sutures (it is expected that this will reduce complications associated with attachment to the surrounding tissues). Moreover, the implants of the invention can be economical to manufacture and highly reproducible, durable, and efficient.

Still further objects and advantages will become apparent from a consideration of the ensuing description and drawings.

BRIEF DESCRIPTION OF THE DRAWINGS

Fig. 1 is a perspective view of a weft knit subassembly.

Fig. 2 is a perspective view of a warp knit subassembly.

Fig. 2A is a perspective view of a weft knit subassembly with an internal support.

Fig. 3 is a perspective view of an implant.

Fig. 4 is a perspective view of a shaped implant.

Figs. 5A-5C are perspective views of implants in various configurations. Fig. 5A illustrates an implant in a collapsed constrained configuration; Fig. 5B illustrates an implant in a collapsed constrained configuration positioned within a bodily defect; and Fig. 5C illustrates an implant in an unconstrained configuration within a bodily defect.

Fig. 6A is a perspective view of a three-dimensional implant with connection means to other implants.

Fig. 6B is a perspective view of the implants connected closely together.

Fig. 6C is a cross-sectional view of the connected implants positioned within a bodily defect.

Fig. 7 is a diagram showing the manufacturing steps.

Figs. 8A-8C are perspective views of implants in various configurations. Fig. 8A is a perspective view of a non-woven subassembly; Fig. 8B is a non-woven three dimensional implant; and Fig. 8C is a side view of a non-woven three-dimensional implant.

Fig. 9A is a diagram of non-woven supports using the Mesh3 design.

Fig. 9B is a diagram of non-woven disks using the Mesh3 design.

Fig. 9C is a diagram of a unit cell of a non-woven soft tissue implant designated Mesh3

Fig. 9D is a display of various measured parameters within Mesh3 and the equations used to calculate the surface area ratio and surface area to volume ratio.

DETAILED DESCRIPTION

The present invention features methods of making and using three-dimensional biocompatible implants, as well as the implants *per se*. An implant, or a subassembly (or collections of subassemblies) therein (*e.g.*, a weft knit subassembly or warp knit subassembly), can be constructed to resist compression when implanted in a warm-blooded animal (*e.g.*, a mammal such as a human) for a period of time (*e.g.*, one to six months, a year, or more).

Weft knit subassemblies can include knit materials that are produced by machine or hand knitting with the fibers running crosswise or in a circle. Warp knit subassemblies can include knit materials that are produced by machine or hand knitting with the yarns running in a lengthwise direction. Either or both subassemblies can be used in the three-dimensional implants of the present invention. As illustrated in the figures below, the subassembly can include woven or braided fibers (including those conforming to the weft knit or warp knit patterns just described) of a biocompatible (*i.e.*, not toxic) material such as a non-absorbable polymer (*e.g.*, polypropylene, polyethylene terephthalate, polytetrafluoroethylene, polyaryletherketone, nylon, fluorinated ethylene propylene, polybutester, silicone, and the like), a nonwoven material of a biocompatible (*i.e.*, not toxic) material such as a non-absorbable polymer (*e.g.*, polypropylene, polyethylene terephthalate, polytetrafluoroethylene, polyaryletherketone, nylon, fluorinated ethylene propylene,

polybutester, silicone, and the like), an absorbable polymer (polyglycolic acid, polylactic acid, polycaprolactone, polyhydroxyalkanoate, polyglyconate, or copolymers thereof (*e.g.*, a PGA:PLA copolymer (the ratio of PGA to PLA can be about 50:50)), a metal (*e.g.*, stainless steel or nitinol), or a tissue-based material (*e.g.*, collagen or a collagen-based or collagen-containing material).

Any of the implants described herein can have an internal support material (*e.g.*, an intraluminal support), such as a polymer (*e.g.*, polypropylene, polyethylene terephthalate, polytetrafluoroethylene, nylon, fluorinated ethylene propylene, silicone, polyurethane, rubber) or a metal (*e.g.*, nitinol). The implant can also include polyaryletherketone (PEEK). PEEK polymer has properties that make it useful in implants of the invention that will be used in or around tissues other than soft tissues. For example, a three-dimensional implant of the invention that includes an internal support material such as PEEK can be used in spine cages, bone screws, orthopedic stems, and dental implants (of course, PEEK-containing implants can be made and used to improve defects in soft tissues as well). Invibio Inc., Lancashire, UK, manufactures PEEK. PEEK offers a desirable combination of strength, stiffness, and toughness, together with extensive biocompatibility. Because the PEEK polymer has enhanced mechanical properties, it is well suited for low material content implants. Soft tissue implants can be fabricated from smaller diameter fibers or thin films with lower profiles than commercially available implants.

The implants (*e.g.*, the subassemblies) can be produced using a circular weft knitting process (with or without an internal support (*e.g.*, with or without an underlying polymer, as described above, in all or a portion of the subassembly)) or a circular warp knitting process. Alternatively, the implants (or subassemblies) can be produced using a braiding process. Alternatively, the implants (or subassemblies) can be produced using a porous biocompatible film with cell patterns having thickness of less than about 0.025 inches (an exemplary cell pattern is shown in Fig. 9C).

The implants can be produced by methods that include one or more of the following steps: extruding a biocompatible polymer into a fiber or film; transforming the fiber or film into a compression resistant subassembly; shaping, braiding, or weaving the subassembly into a three dimensional structure; heat setting the structure into the desired shaped article; and, optionally, attaching the shaped article to a

complementary implant article (*e.g.*, an anchor). These steps can be performed in the order given. The methods can also include removing shaping mandrels, internal supports, or intraluminal supports (where such are used, at, for example, the completion of the shaping, braiding, or weaving process).

As noted elsewhere, the subassemblies can include pores of, for example, 50-2000 microns in diameter (when the implant is placed in a resting or non-compressed position). The implant can assume any number of forms, which may be tailored for use in particular parts of the body or in response to certain defects. For example, the implant can have a conical form (as shown, for example, in Figs. 8A, 8B, and 8C).

The implant subassembly can have a surface area ratio less than 3.0 (*e.g.*, 0.50 – 3.0 or, for example, about 1.0), and the implant (or one or more of the subassemblies therein) can include an additional component such as an onlay or anchor or other means for stabilizing the implant during placement within a warm-blooded animal. The implants (or one or more of the subassemblies therein) can be connected to one or more implant components (*e.g.*, an onlay and/or anchor) in a manner that permits independent placement and stabilization of the implants.

The methods of the invention (the methods of generating a three-dimensional implant and the methods for implanting that implant into a patient) can be used to repair essentially any defective tissue. For example, a three-dimensional biocompatible implant described herein can be applied to a tissue defect by way of a surgical procedure (these procedures will be analogous to those carried out in the art using different types of implants). The patient being treated may have, for example, a hernia or other tissue rupture, tear, or defect. The methods can include exposing a defective tissue on or within the patient's body and placing the implant on or over the tissue; before or during placement, the implant can be compressed, by hand or by a device.

Biocompatible fibers (used in, for example, the subassemblies) can be produced using a melt extrusion process. Luxilon Industries NV (Wijnegem, Belgium) produces medical grade fiber suitable for this application. Luxilon produces polypropylene fiber used for implants. Lamb Knitting Machine Corporation (Chicopee, MA) produces knitting equipment suitable for this processing step. The fiber is converted using either a circular weft-knitting machine or a warp knit braider.

The weft or warp knit subassemblies, with or without an intraluminal support (*e.g.*, a polymer support such as PEEK polymer), can be braided into a three-dimensional implant structure. For example, Wardwell Braiding Machine Company located in Central Falls, Rhode Island produces braiding equipment suitable for this processing step.

The braided three-dimensional implant structure can be heat set into a more stable structure by heating the three-dimensional implant structure above its glass transition temperature. A suitable temperature for polypropylene materials is 150°C. Mandrels can be used to support the subassemblies so that a desired shape with predetermined dimensions is produced.

Biocompatible films (used in, for example, the subassemblies) can be produced using an extrusion and orientation process. Bard Peripheral Vascular (Tempe, AZ) produces expanded polytetrafluoroethylene film suitable for this application. The film can be machined into a design with cell patterns to impart a higher degree of porosity with a lower implant surface area ratio. The film can be converted into a three-dimensional object (*e.g.*, a cylinder, cone, sphere, or block (*e.g.*, an essentially square or rectangular block) using a cutting and heat setting process.

Medical implant applications for the soft tissue implant technology described above may include, but are not limited to, plastic reconstruction, hernia repair, vessel occlusion and other soft tissue reconstruction procedures where biocompatible fillers are required. The soft tissue implant can be produced in a variety of shapes and sizes for the particular indications. The shaped article can also be used for blood filtration applications. Non-medical applications may include diagnostic, biotechnology, automotive, electronics, aerospace, and home and commercial appliances applications.

Referring now to the figures:

Fig. 1 is a perspective view of weft knit subassembly **14**. The weft knit subassembly is made from biocompatible fiber **16** and has a known design and fiber count. Fiber count is characterized through needle and stitch densities for the material. The weft knit subassembly **14** is made of a biocompatible material.

Fig. 2 is a perspective view of a warp knit subassembly **18**. The warp knit subassembly **18** is made from biocompatible fiber **16** and has a known design and fiber count. The warp knit subassembly **18** is made of a biocompatible material.

Fig. 2A is a perspective view of a weft knit subassembly **14** with intraluminal support **15**. Biocompatible fibers **16** are found external to and, optionally, in physical connection with intraluminal support **15**. Intraluminal support **15** can provide a compression resistant structure during processing, and can be composed of a material that permits post-processing.

Fig. 3 is a perspective view of three-dimensional implant **20**. Weft knit subassembly **14** has been converted into braided three-dimensional implant **20** using braiding equipment.

Fig. 4 is a perspective view of shaped three-dimensional implant **22** (a conical implant). The braided three-dimensional structure has been heat set into a shaped three-dimensional implant **22** by placing shaping mandrels in the weft knit subassemblies **14** (composed of biocompatiable fiber **16**) and applying heat.

Fig. 5A is a perspective view of a constrained three-dimensional implant **24**. The implant is collapsed and constrained by a hollow tube **26** to prevent expansion of the weft knit subassemblies **14**.

Fig. 5B is a perspective view of a constrained three-dimensional implant **24** positioned in a bodily defect **28**.

Fig. 5C is a perspective view of a shaped three-dimensional implant **22** unconstrained and filling the bodily defect **28**.

Fig. 6A is a perspective view of a shaped three-dimensional implant **22**, implant onlay **30**, and anchor **34** connected together with connecting filament **32** that permits individual placement of separate structures.

Fig. 6B is a perspective view of a shaped three-dimensional implant **22**, implant onlay **30**, and anchor **34** connected together with connecting filament **32** that prevents migration of the individual components.

Fig. 6C is a cross sectional view of a shaped three-dimensional implant **22**, implant onlay **30**, and anchor **34** connected together with connecting filament **32** positioned in a bodily defect **28**.

Fig. 7 is a diagram showing one possible combination of manufacturing steps.

Fig. 8A is a perspective view of a non-woven subassembly with biocompatible disks **40** and support members **42**. Both disks **40** and support members **42** have openings **43**, which allow the subassembly to slide together.

Fig. 8B is a perspective view of a non-woven three-dimensional implant with biocompatible disks **40** and support members **42**.

Fig. 8C is a side view of a non-woven three-dimensional implant with biocompatible disks **40** and support members **42**.

Fig. 9A is a diagram of non-woven supports **50** machined using the Mesh3 design with openings **43** to permit assembly. Pores **49**

Fig. 9B is a diagram of non-woven disks **40** using the Mesh3 design with openings **43** which accommodate the support members.

Fig. 9C relates to a non-woven soft tissue implant designated Mesh3.

Fig. 9D is a display of various measured parameters within Mesh3 and the equations used to calculate the surface area ratio and surface area to volume ratio.

EXAMPLE

Example 1: A three-dimensional non-woven soft tissue implant was constructed using a biaxially-oriented polymer film. The film is stretched in both the machine and transverse directions (relative to the extrusion direction) to orient the polymer chains. The stretching process can take place simultaneously or sequentially depending on the equipment that is available. The base film was Syncarta™ (AET Films, Peabody, MA). The base film was machined into Mesh Design 3 ("Mesh3") using a 3.0-Watt Avia Q-switched Ultraviolet Laser produced by Coherent, Inc. (Santa Clara, CA). The design of a cell for the non-woven soft tissue implant is shown in Fig. 9C. The soft tissue implant was cut into circular disks and triangular supports used to construct a three-dimensional implant. The calculation for the surface area for the components used to construct the three-dimensional implant is shown in Fig. 9D.

$V_{implant} = ((\Pi)(L_{implant})(R_{implant})^2)/3$ where $V_{implant}$ is the volume of the cone shaped implant, $L_{implant}$ is the implant height, and R_{imlant} is the implant radius at the base; and

Surface Area to Volume Ratio = $A_{surface\ implant}/V_{implant}$.

Product	Implant Surface Area (cm^2)	Implant Volume (cm^3)	Surface Area to Volume Ratio
Three Dimensional Implant (Mesh Design 3)	53.89	21.61	2.49

Although the description above contains many specificities, these should not be construed as limiting the scope of the invention but as merely providing illustrations of some of the presently preferred embodiments of this invention. For example, the implant can have other subassembly designs, different materials can be utilized, and alternate equipment can be used to produce the structures, etc.

What is claimed is:

1. A three-dimensional biocompatible implant, the implant comprising a subassembly that resists compression when implanted in a warm-blooded animal.

2. The implant of claim 1, wherein the subassembly comprises woven or braided fibers.

3. The implant of claim 1, wherein the subassembly is produced using a circular weft knitting process.

4. The implant of claim 3, wherein the subassembly is produced using a circular weft knitting process with an internal support.

5. The implant of claim 3, wherein the subassembly is produced using a circular weft knitting process without an internal support.

6. The implant of claim 1, wherein the subassembly is produced using a circular warp knitting process.

7. The implant of claim 1, wherein the subassembly is produced using a braiding process.

8. The implant of claim 1, wherein the subassembly is produced using a nonwoven film and/or wherein the subassembly comprises pores.

9. The implant of claim 8, wherein the pores are 50-2000 microns in diameter.

10. The implant of claim 9, wherein the implant has a conical form.

11. The implant of claim 1, wherein the implant comprises polyaryletherketone.

12. The implant of claim 1, further comprising an onlay

13. The implant of claim 1, further comprising an anchor.

14. The implant of claim 1, further comprising a means for stabilizing the implant during placement within a warm-blooded animal

15. A method for producing a three-dimensional biocompatible implant, the method comprising one or more of the following steps:

a) extruding a biocompatible polymer into a fiber,
b) transforming the fiber into a compression resistant subassembly,
c) braiding or weaving the subassembly into a three dimensional structure,
d) heat setting the structure into the desired shaped article, and, optionally,
e) attaching the shaped article to a complementary implant article.

16. The method of claim 15, further comprising removing shaping mandrels or intraluminal support.

17. A method for repairing a defective tissue in a patient, the method comprising applying the three-dimensional biocompatible implant to the defect by way of a surgical procedure.

18. The method of claim 17, wherein the patient has a hernia.

19. A kit comprising an implant of claim 1, wherein the implant is sterile.

20. A method of delivering the implant of claim 1 to a patient's body, the method comprising exposing a defective tissue on or within the patient's body and placing the implant on or over the tissue.

21. The method of claim 20, wherein the implant is compressed, by hand or by a device, prior to being placed on or over the tissue.

22. A method for producing a three-dimensional biocompatible implant, the method comprising one or more of the following steps:

a) extruding a biocompatible polymer into a film,
b) transforming the film into a subassembly,
c) shaping the subassembly into a three dimensional structure,
d) heat setting the structure into the desired shaped article, and, optionally,
e) attaching the shaped article to a complementary implant article.

23. The implant of claim 1, wherein the implant has a surface area to volume ratio less than about 5.0.

24. The three dimensional implant of claim 23, wherein the surface area to volume ratio is less than about 4.0, less than about 3.0, less than about 2.0, or is about 1.0.

25. The three-dimensional implant of claim23, wherein the biocompatible material comprises a non-absorbable polymer or copolymer.

26. The three-dimensional implant of claim25, wherein the non-absorbable polymer or copolymer comprises polypropylene, polyethylene terephthalate, polytetrafluoroethylene, polyaryletherketone, nylon, fluorinated ethylene propylene, polybutester, or silicone.

27. The three-dimensional implant of claim 23, wherein the biocompatible material comprises an absorbable polymer or copolymer.

28. The three-dimensional implant of claim 27, wherein the absorbable polymer or copolymer comprises polyglycolic acid (PGA), polylactic acid (PLA), polycaprolactone, or polyhydroxylkanoate.

29. The three-dimensional implant of claim 23, wherein the biocompatible material comprises a biological material.

30. The three-dimensional implant of claim 29, wherein the biocompatible material is collagen.

31. A three-dimensional implant comprising two or more layers of two-dimensional biocompatible material with interconnecting supports, said implant constructed to securely fit within a tissue or muscle wall defect.

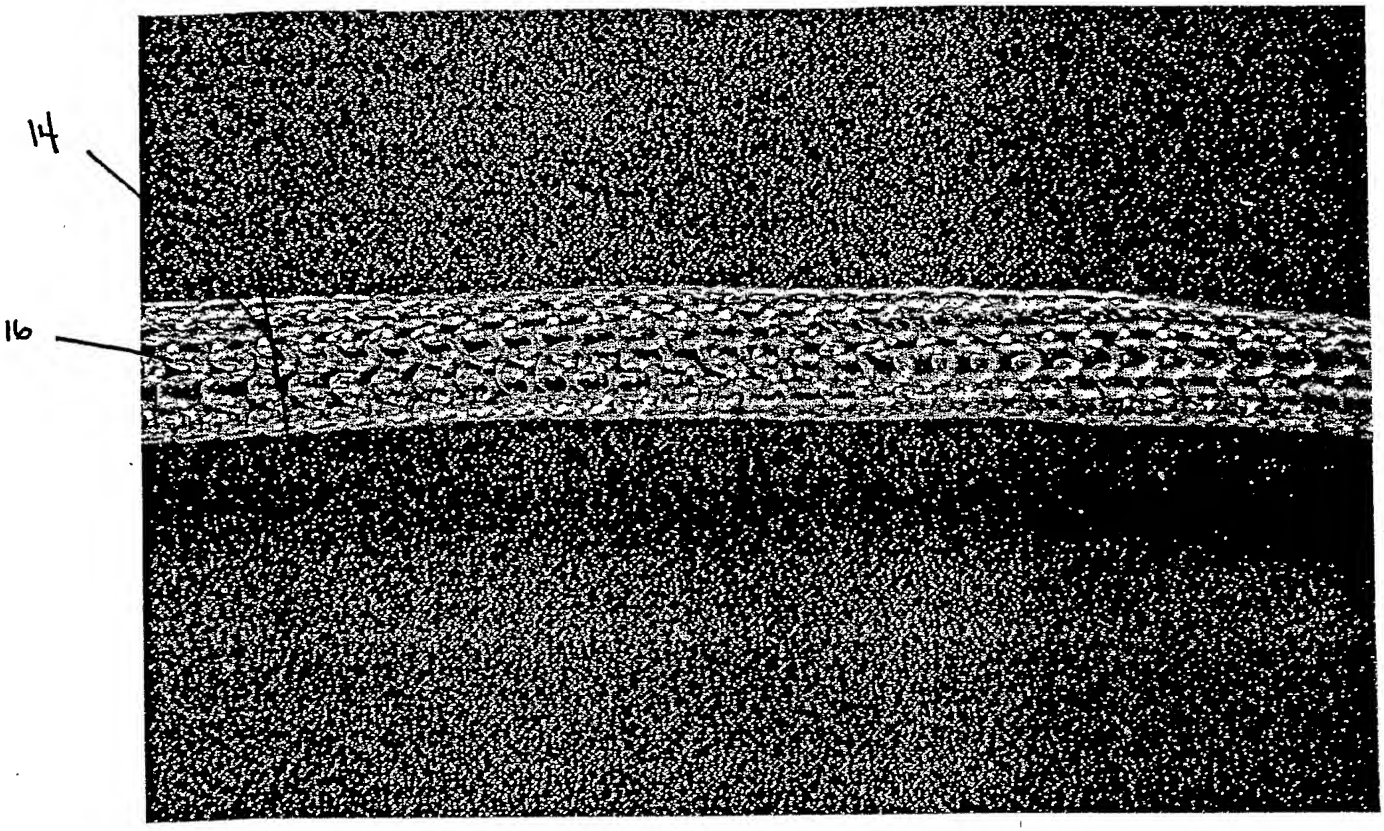

Fig. 1

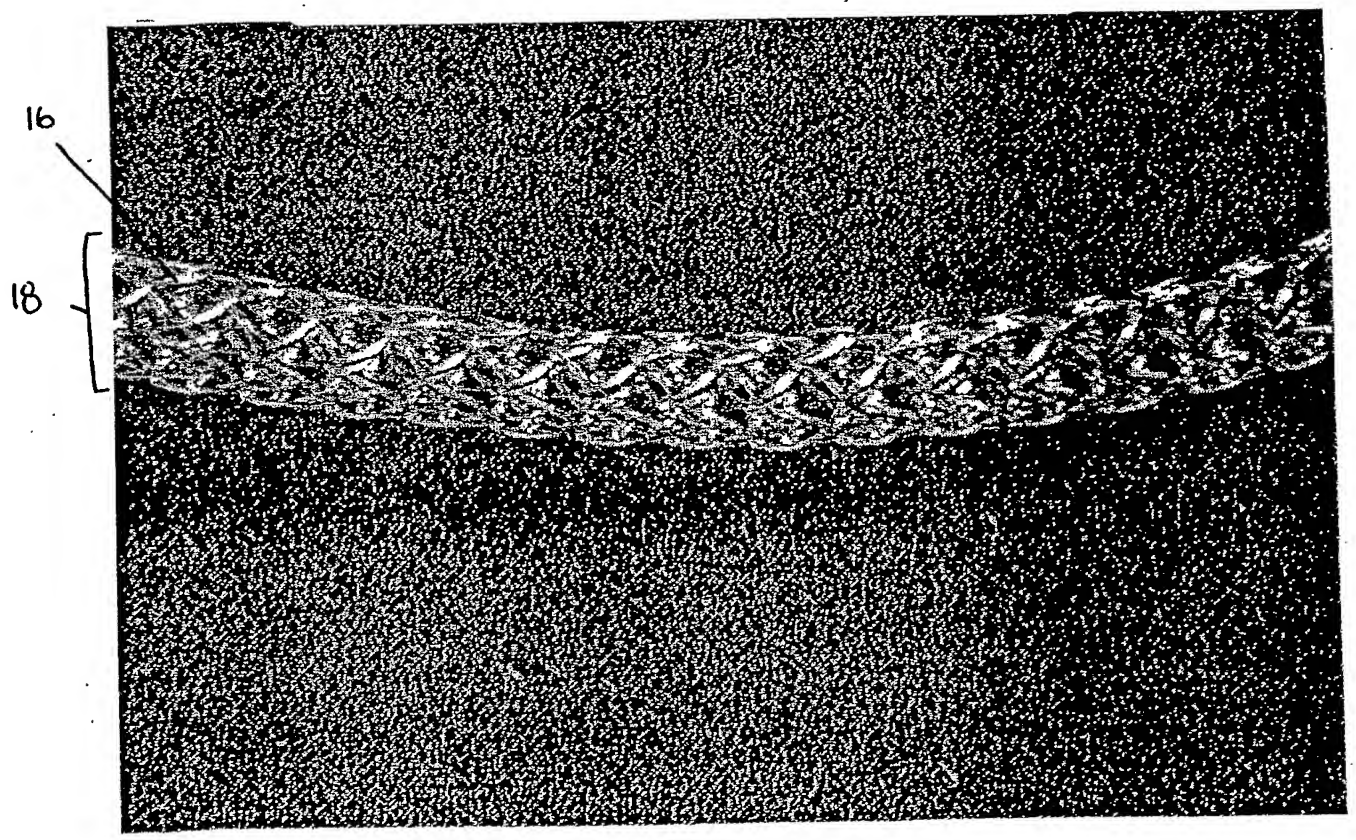

Fig. 2

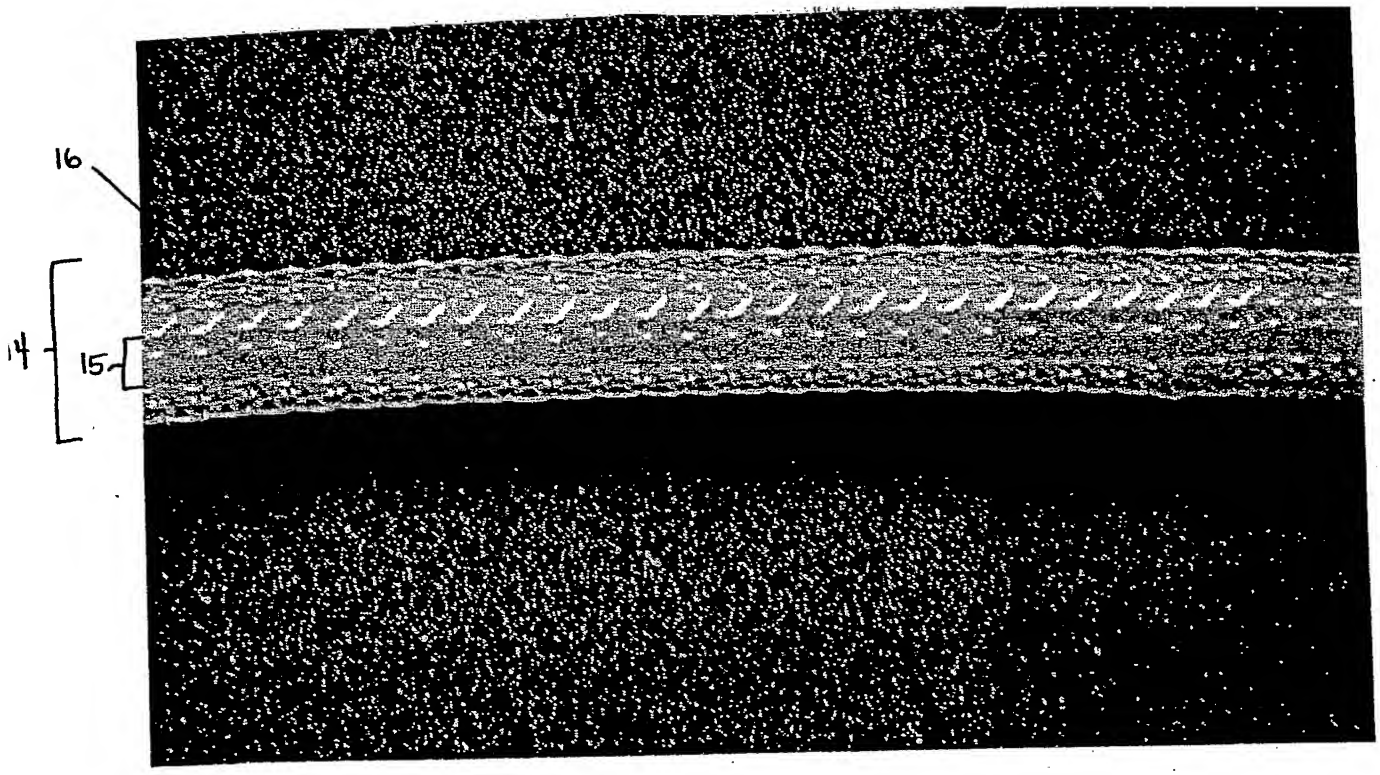

Fig. 2A

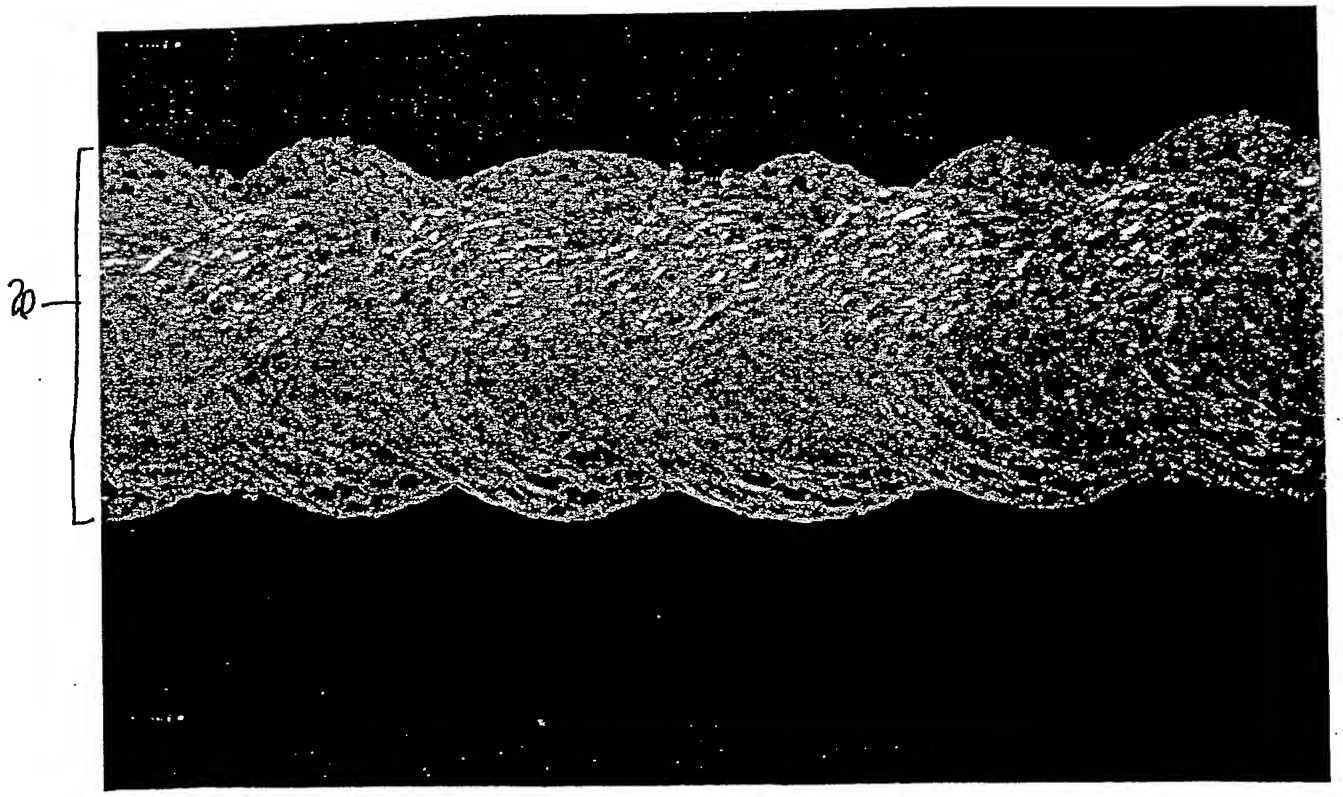

Fig. 3

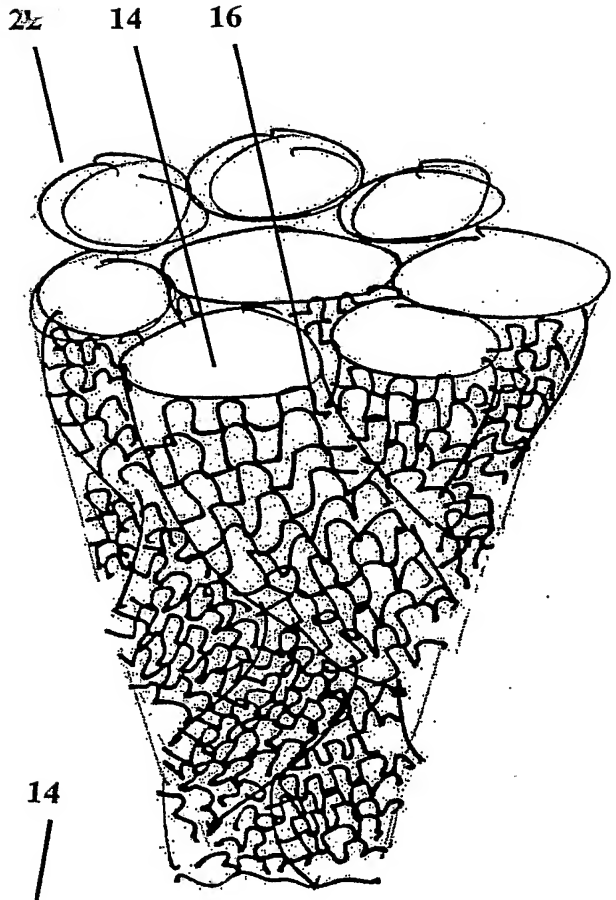

FIG 4

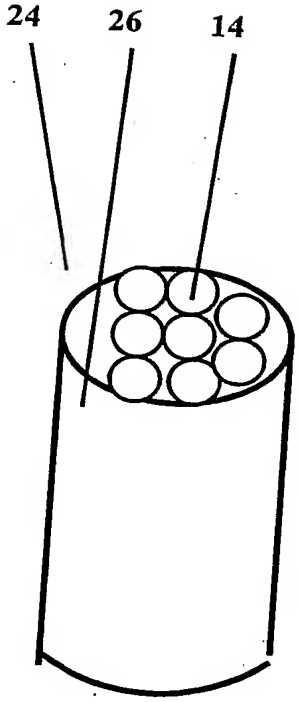

FIG 5A

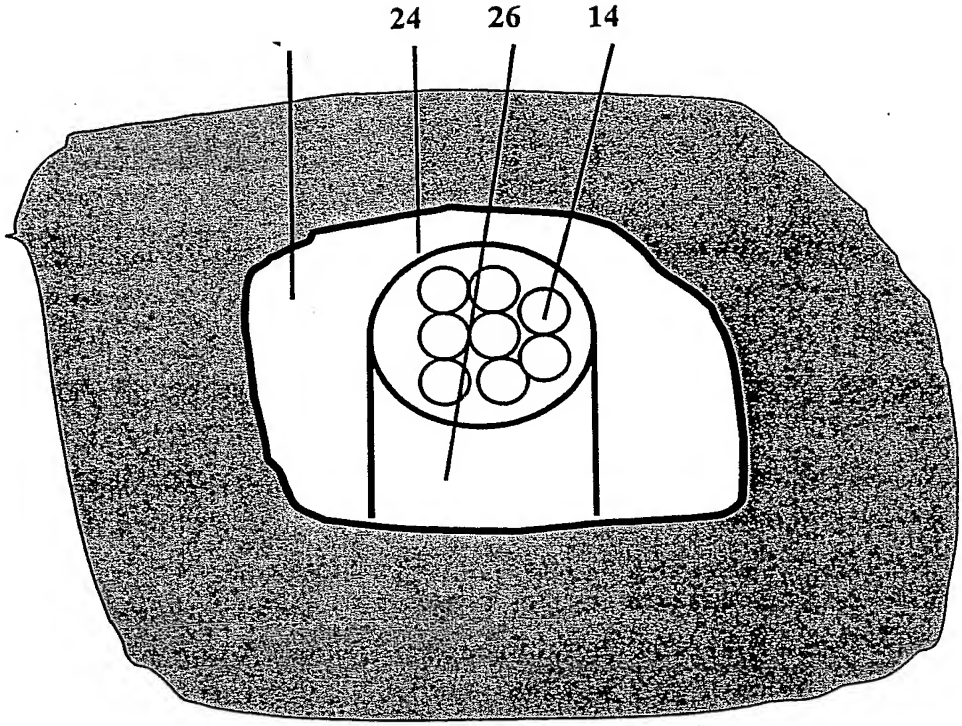

FIG 5B

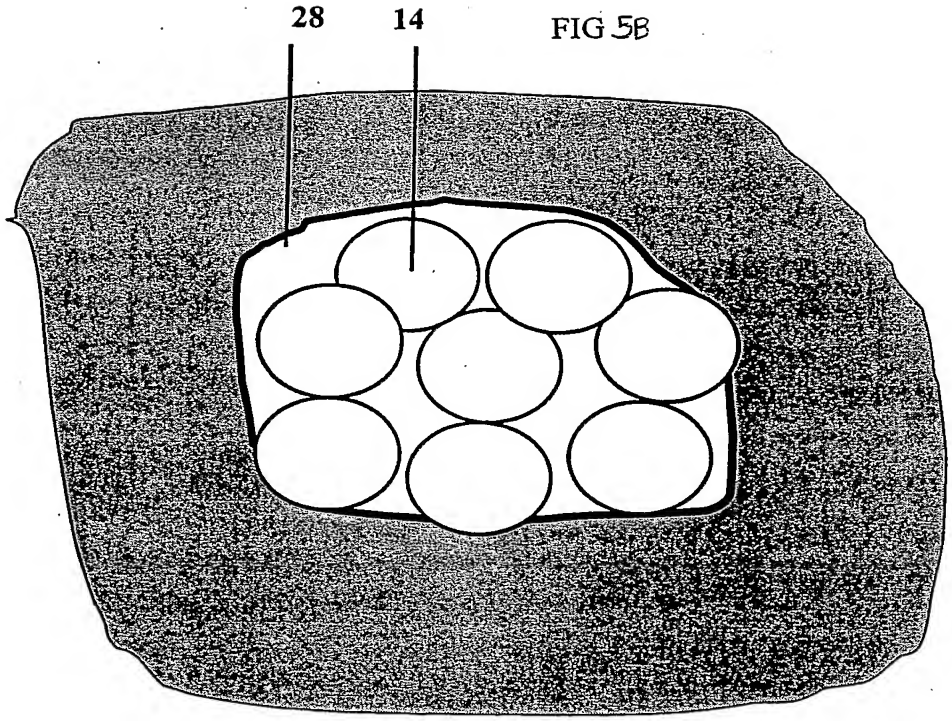

FIG 5C

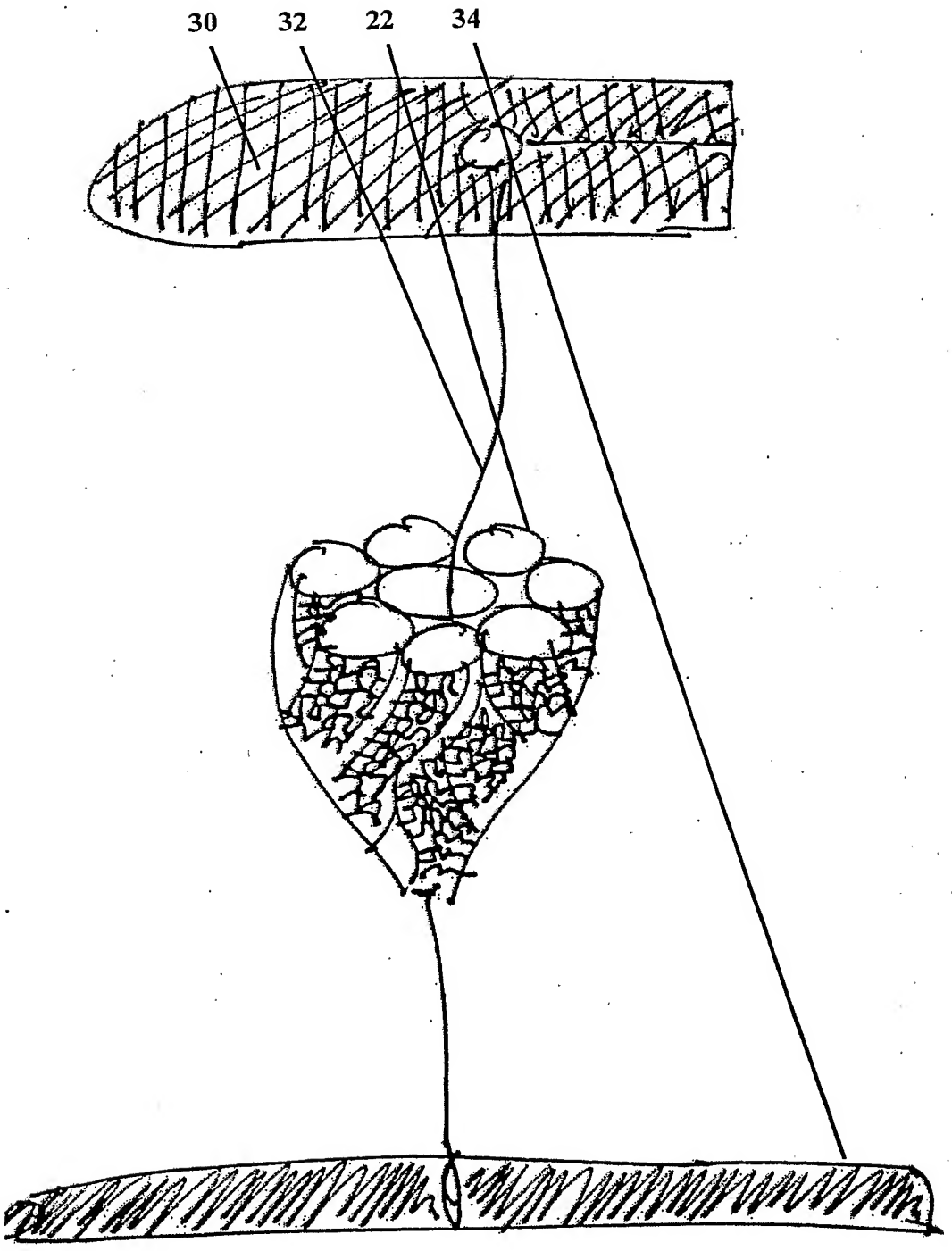

FIG 6A

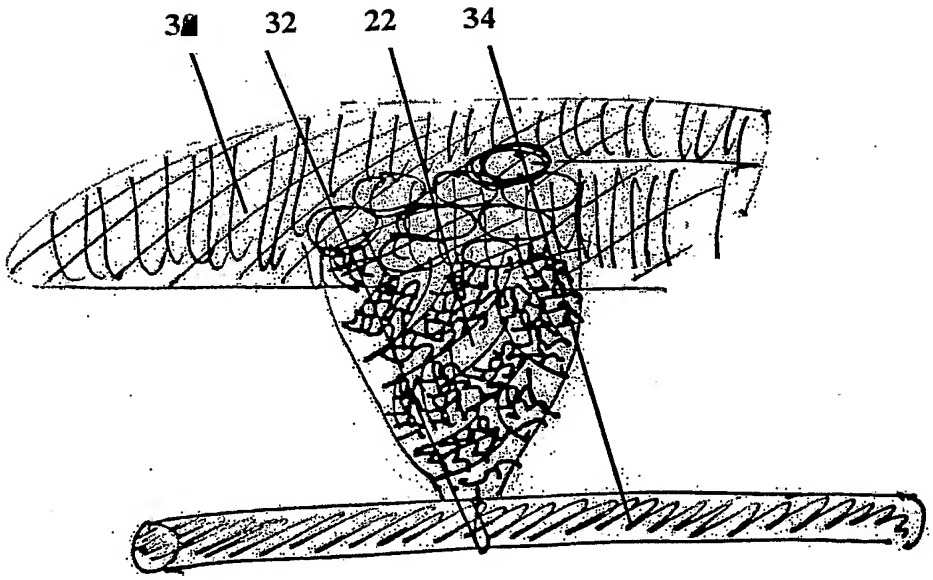

FIG 6B

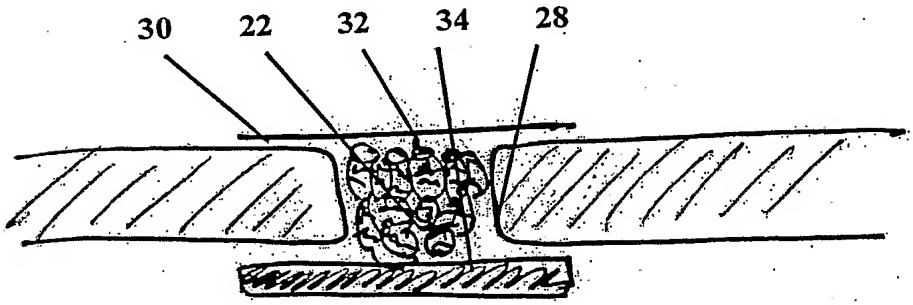

FIG. 6C

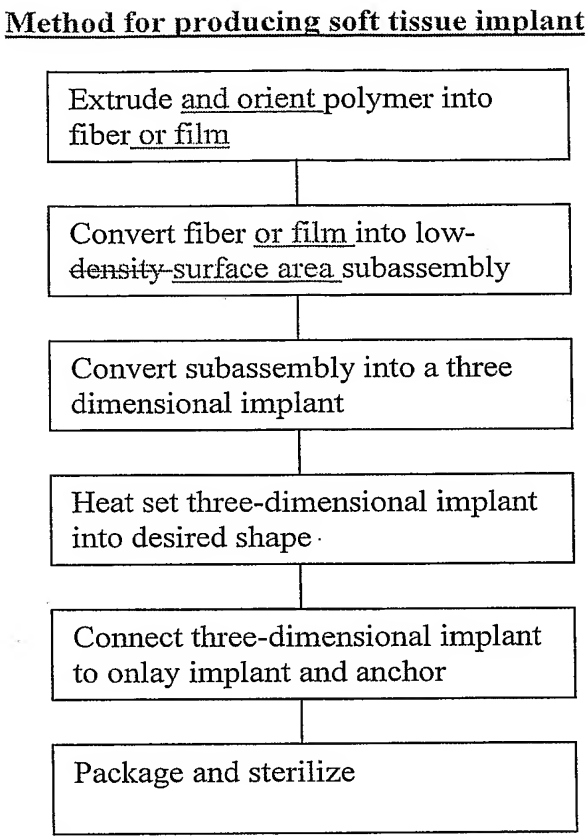
Method for producing soft tissue implant
Extrude and orient polymer into fiber or film
Convert fiber or film into low-density surface area subassembly
Convert subassembly into a three dimensional implant
Heat set three-dimensional implant into desired shape
Connect three-dimensional implant to onlay implant and anchor
Package and sterilize

FIG. 7

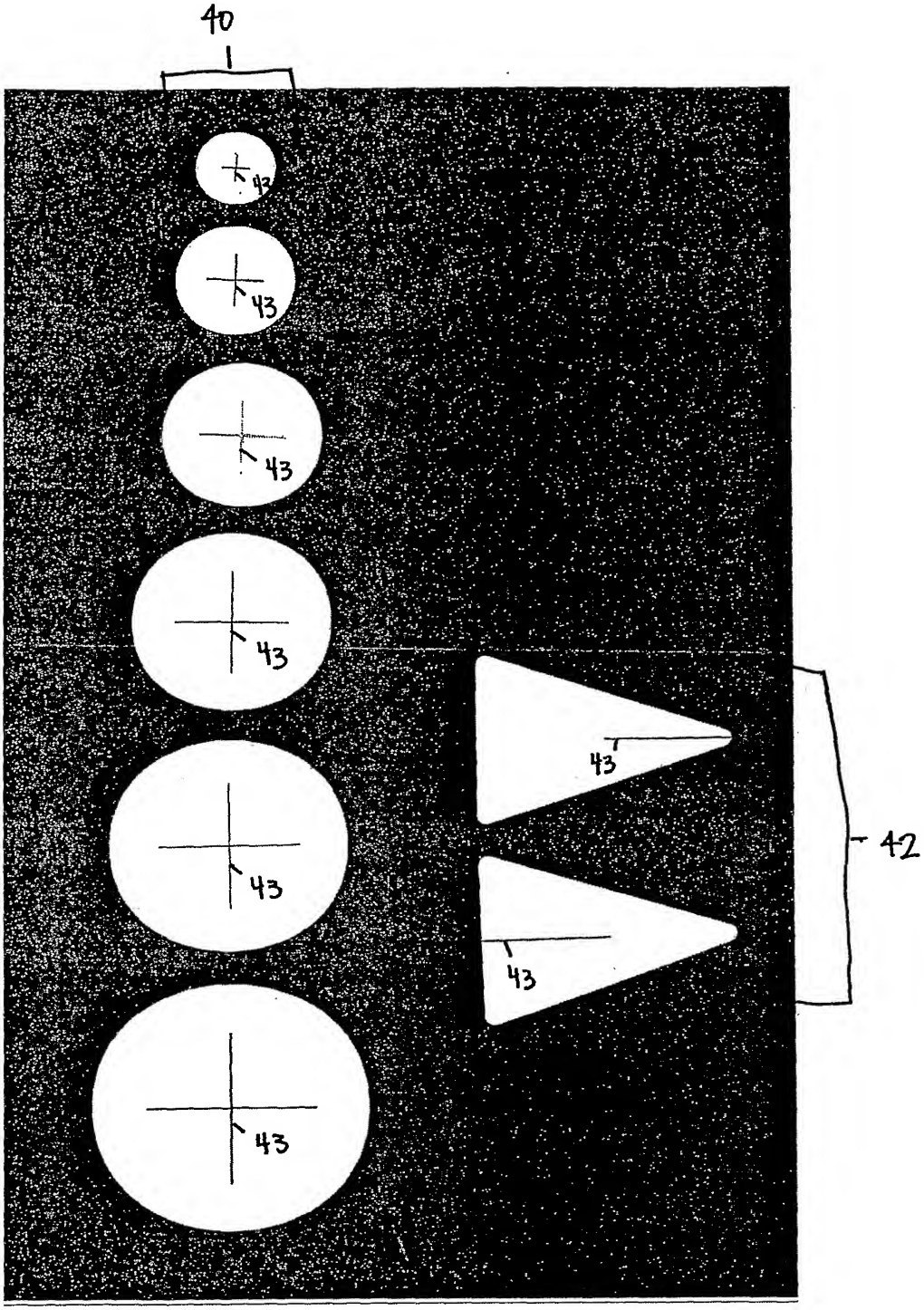

Figure 8A

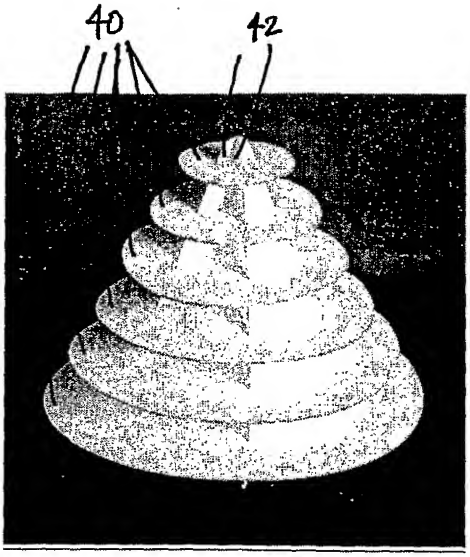

Figure 8B

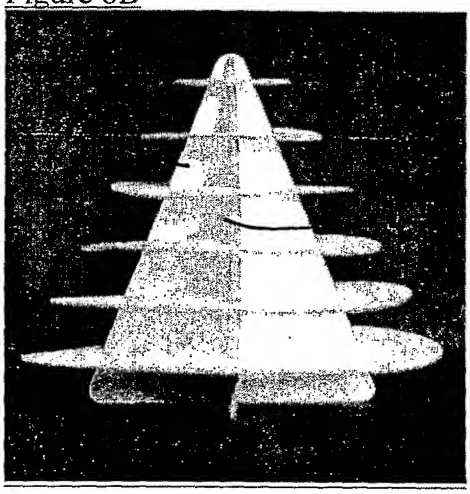

Figure 8C

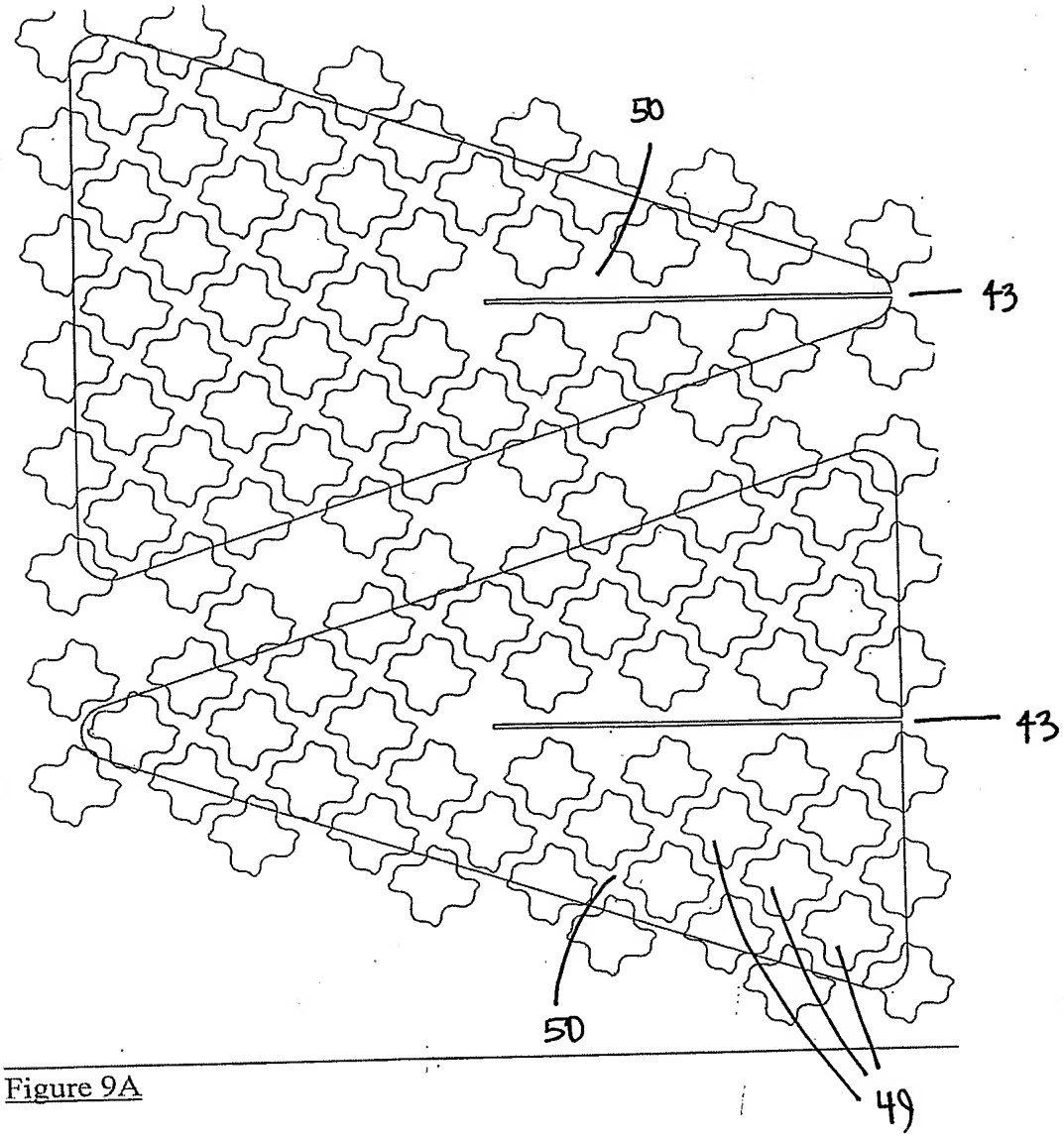

Figure 9A

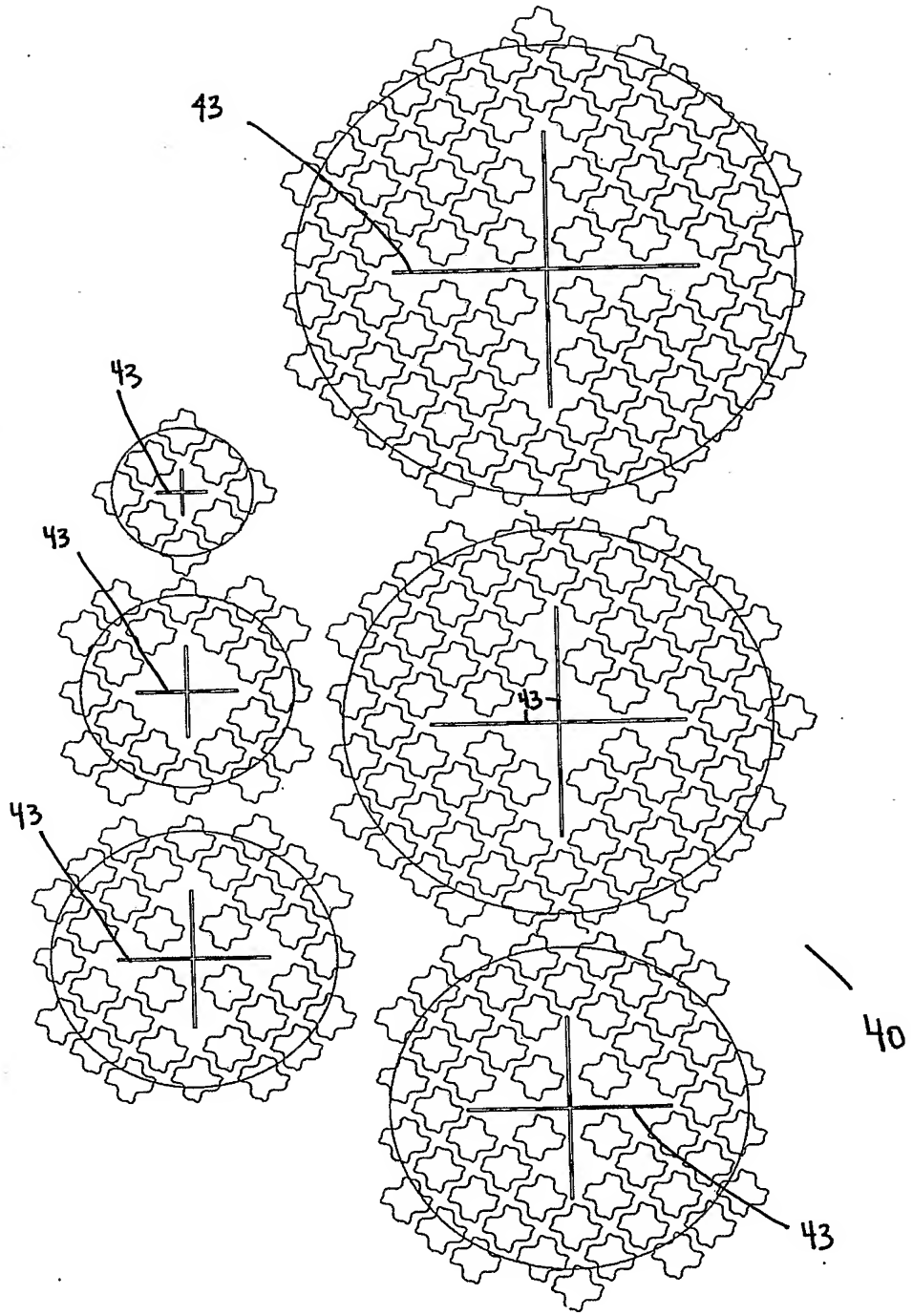

Figure 9B

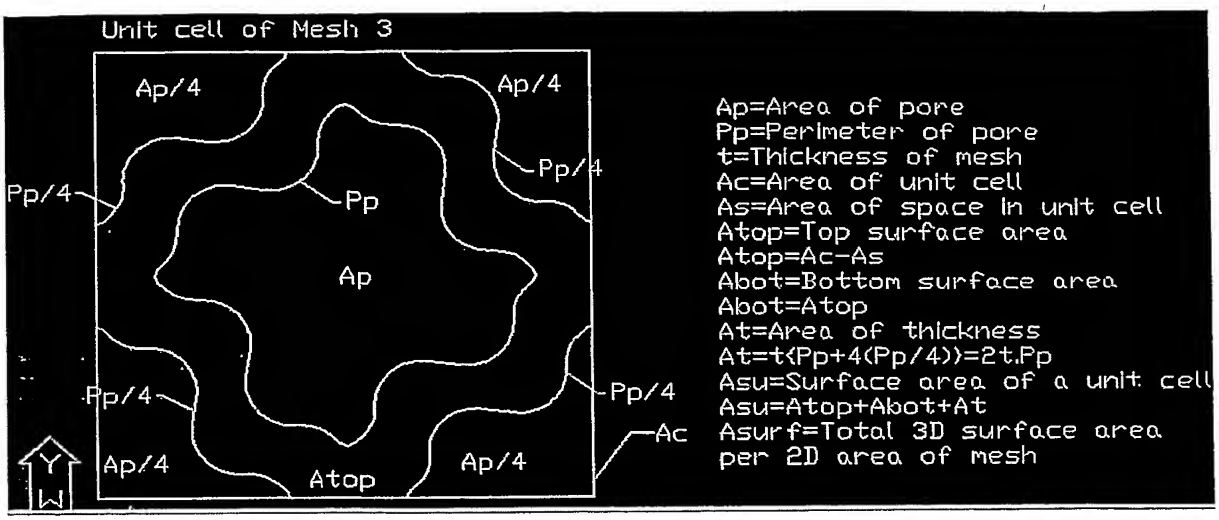

Fig. 9C

Method for Calculating Mesh3 Surface Area

Area of pore	Ap	10.89	mm2
Perimeter of pore	Pp	15.08	mm
Thickness	t	0.20	mm
Area of unit cell	Ac	35.48	mm2

Area of space in unit cell	As=Ap+4(Ap/4)=2Ap	21.78	mm2
Top surface area	Atop=Ac-As	13.70	mm2
Bottom surface area	Abot=Atop	13.70	mm2
Area of thickness	At=t(Pp+4(Pp/4))	6.03	mm2

3D surface area of a unit cell	Asu=Atop+Abot+At	33.43	mm2
Surface area ratio	Asurf=Asu/Ac	0.94	

Method for Calculating the Surface Area for the Three Dimensional Implant Components

Area of disks	$Ad=\pi(r_1)^2+\pi(r_2)^2+\ldots$	44.02	cm2

Surface area of disks	Asurfd=Ad*Asurf	41.38	cm2
Area of supports	As=((Lsup*Rsup)*1/2)*2	13.31	cm2
Surface area of supports	Asurfs=As*Asurf	12.51	cm2
Surface area of implant	Asurfi=Asurfd+Asurfs	53.89	cm2

Fig. 9D

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US03/26905

A. CLASSIFICATION OF SUBJECT MATTER

IPC(7) : A61F 2/06
US CL : 623/1.15, 1.13, 1.5, 1.51, 1.53, 1.44

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
U.S. : 623/1.15, 1.13, 1.5, 1.51, 1.53, 1.44

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)
EAST - stent, braided, micron, pores, polyaryletherketone

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	US 6,436,132 B1 (Patel et al.) 20 August 2002, see figures 1-4	1-9, 12, 31
---		---
Y		10, 11, 13-30
X	US 5,980,564 A (Stinson) 9 November 1999, see figures 1-5	1-8, 12
---		---
Y		9-11, 13-31

☐ Further documents are listed in the continuation of Box C. ☐ See patent family annex.

* Special categories of cited documents:

"A" document defining the general state of the art which is not considered to be of particular relevance

"E" earlier application or patent published on or after the international filing date

"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)

"O" document referring to an oral disclosure, use, exhibition or other means

"P" document published prior to the international filing date but later than the priority date claimed

"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention

"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone

"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art

"&" document member of the same patent family

Date of the actual completion of the international search	Date of mailing of the international search report
01 December 2003 (01.12.2003)	21 JAN 2004
Name and mailing address of the ISA/US Mail Stop PCT, Attn: ISA/US Commissioner for Patents P.O. Box 1450 Alexandria, Virginia 22313-1450 Facsimile No. (703)305-3230	Authorized officer (Jackie) Tan-Uyen T. Ho Telephone No. (703) 308-0858

Form PCT/ISA/210 (second sheet) (July 1998)